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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,591	06/27/2001	Tillman U. Germgross	GFI 100	2292

7590 10/02/2002

Patrea L. Pabst  
Holland & Knight LLP  
2000 One Atlantic Center  
1201 West Peachtree Street  
Atlanta, GA 30309-3400

EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/892,591	GERNGROSS, TILLMAN U.
Examiner	Art Unit	
Celine X. Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) 1-34 are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### **Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### **Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

Claims 1-34 are pending in the application.

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to a method of producing glycoprotein having carbohydrate structures similar to human cells by introducing one or more enzymes for production of said carbohydrate structure into a fungal host lacking said enzymes, classified in class 435, subclass 183.
- II. Claims 24-31, drawn to a method of producing glycoprotein having carbohydrate structures similar to human cells by transforming the fungal host with a DNA library comprising at least two genes encoding exogenous distinct enzymes for production of said carbohydrate structure, classified in class 435, subclass 471.
- III. Claim 32, drawn to a host comprising one or more enzymes for production of carbohydrate structure similar to those produced by a human cell, classified in class 435, subclass 254.11.
- IV. Claim 33, drawn to a glycoprotein produced by the fungal host which is structurally similar to a glycoprotein produced by a human cell, classified in class 530, subclass 395.
- V. Claim 34, drawn to a library comprising at least two genes encoding glycosylation enzymes, classified in class 435, subclass 6.

The inventions are distinct, each from the other for following reasons.

The inventions of Group I and II are patentably distinct because the inventions are drawn to methods that require different starting materials and modes of operation. The methods of Group I and II require different method steps, for example, introducing protein into a host cell vs. introducing a DNA library into a host cell. Therefore, the invention of Groups I and II are patentably distinct.

The inventions of Groups III, IV and V are patentably distinct from each other because the inventions are drawn to materially distinct compositions that are not related. A fungal host cell, a glycoprotein and a library are chemically, biologically and functional distinct from each other. Therefore, the inventions of Groups III-V are patentably distinct.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the glycoprotein can also be made in mammalian cells. Therefore, the inventions of Groups I and IV are patentably distinct.

The inventions of Groups I, II and Groups II, IV, V are patentably distinct because the inventions are drawn to compositions and methods that are not directly related. Although the library of Group V can be used in the method of Group II, the method of Group II can also be practiced by introducing glycoenzymes directly into the host cells. Therefore, the inventions of Groups I, II and Groups II, IV, V are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for

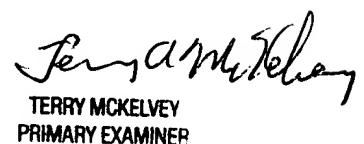
examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
September 25, 2002

  
TERRY MCKELVEY  
PRIMARY EXAMINER